

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants(s) : ANDERSEN et al.
U.S. Serial No.: 09/805,427
Filing Date : March 13, 2001
For: : HYBRIDS OF M. TUBERCULOSIS ANTIGENS
Examiner : Rodney P. Swartz, Ph.D.
Art Unit : 1645

670001-2002.5
10/14/03

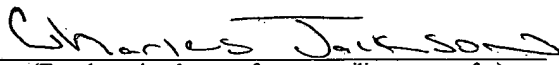
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New York, NY 10151

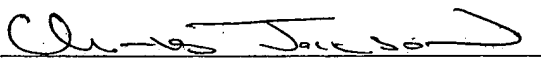
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COMMUNICATION AND INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Communication is supplemental to the Response filed May 29, 2003.

The Office Action mailed December 30, 2002, contained an assertion that "the only examples taught in the instant specification do not involve protection of human against infection with M. tuberculosis, but only laboratory animals, i.e. guinea pigs, mice, and monkeys, which are not hosts for normal infection with M.tb." Office Action at 7.

The Examiner's attention is respectfully directed to the document set forth on the accompanying form PTO-1449. Walsh *et al.* describes the use of the Philippine cynomolgus monkey as an excellent model of chronic TB. When challenged with moderate or low doses of *M. tuberculosis*, the Philippine cynomolgus monkeys developed a chronic, slowly progressive and localized form of pulmonary TB which closely resembles TB in humans clinically, immunologically, and pathologically. Additionally, a significant number of challenged monkeys developed the infection in a subclinical state, which corresponds to the large percentage of humans who when exposed to TB contain the infection and do not develop overt disease.

Hence, Walsh *et al.* demonstrate that monkeys are an ideal model for tuberculosis infection in humans.

This Information Disclosure Statement is being filed after receipt of a non-final Office Action mailed December 30, 2002, and we have enclosed the required fee of \$180.00 set forth in §1.17(p) for consideration and entry of this document. However, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account 50-0320.

The filing of this Information Disclosure Statement is not an admission that the document identified herein constitutes prior art to the present application.

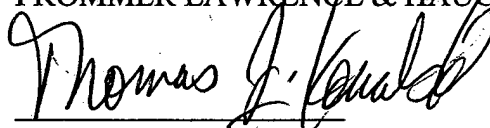
Applicants respectfully request that the Examiner considers and makes of record the document cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

And, Applicants request that the rejections under 35 U.S.C. §112, first paragraph be reconsidered and withdrawn in view of the enclosed document which demonstrates that monkeys are an ideal and preferred model for tuberculosis infections in humans.

Respectfully submitted,

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